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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,963	08/15/2006	Paolo Alberto Veronesi	1PU1954-009	8586

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STANDLEY LAW GROUP LLP
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Dublin, OH 43017

EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
11/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,963	VERONESI, PAOLO ALBERTO	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-14,16,17 and 32* is/are pending in the application.

4a) Of the above claim(s) *2,15 and 18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-14,16,17 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 09/13/2010.

Claims 1-3 and 5-32 are pending.

Claims 2, 15, and 18-31 are withdrawn.

Claim 32 is newly added.

Claim 4 is cancelled.

Claims 1, 8, and 12 are currently amended.

Claims 1, 3, 5-14, 16, 17, and 32 are currently under consideration.

Withdrawn Rejections and/or Objections

The rejection of claims 8 and 12 under 35 U.S.C. 112 second paragraph for the terms "optimally" and "preferably" has been withdrawn in view of Applicant's deletion of said terms from said claims.

The objection of claim 17 has been withdrawn in view of Applicant's amendments to the claims.

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) is withdrawn in view of Applicant's cancellation of said claim.

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) as applied to claims 1, 3-

12, 14, 16, and 17 above, and further in view of Lundberg et al (U.S. Patent number 6,013,281, patent issued Jan. 11, 2000) is withdrawn in view of Applicant's cancellation of said claim.

New Grounds of Rejection – Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites "[t]he pharmaceutical preparation according to claim 8, wherein at least one of the following obtains:

cetylpyrridinium chloride is present at about 5.0 mg/ml; and

glycyrrhizic acid is present at about 1.0 mg/ml.

It is unclear what is intended by said claim. The recitation of the term "obtains" casts doubt as to whether said claim is directed to a product or a process limitation. It is unclear, in view of claim 8, whether said cetylpyrridinium chloride and glycyrrhizic acid are required elements, and if so, are both required as implied by "and" or is it merely "at least one". For the sake of compact prosecution, said claim is interpreted as being directed to requiring at least one of the two recited components.

Maintained Rejections

-note: New Grounds for newly added claim 32

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-12, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference).

Pinza teaches an aqueous mouthwash or oral spray (see entire document, especially page 3, lines 22-23 and claim 1). Said composition comprising tromethamine and a salt of diclofenac, wherein the pH of the composition is between 7 and 8 (see entire document, for instance claim 1). Said composition further comprises sweeteners such as sodium saccharinate, sorbitol, xylitol (see entire document, for instance claim 3). Said composition further comprises a preserving agent, specifically sodium

benzoate, methyl p-hydroxybenzoate, or propyl p-hydroxybenzoate (see entire document, for instance claim 4). Said, for instance, sodium benzoate is exemplified as being present in an amount of 5 mg/ml (see entire document, for instance, example 1). Said diclofenac is taught as being present in an amount of 0.1 to 0.2% (see entire document, for instance claim 1, also note percentages in table 1 of instant specification). Said tromethamine is exemplified as being present in an amount of approximately a third of that of the diclofenac (see for entire document, for instance page 2, lines 13-17), note that the instant claims utilize the term "about" with regard to the amount of tromethamine present.

Pinza fails to directly teach that the non-steroidal anti-inflammatory drug is flurbiprofen.

Caldwell teaches an oral composition comprising a non-steroidal anti-inflammatory, specifically, either diclofenac, flubiprofen, naproxen, or ketoprofen (see entire document, for instance claims 1 and 3). Caldwell further teaches the use of TRIS (tromethamine) buffer in said composition (see entire document, for instance examples 9 and 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the flubiprofen of Caldwell in the invention of Pinza. One would have been motivated with a reasonable expectation of success to either utilize the flubiprofen in place of the diclofen, or utilize the flubiprofen in combination with the diclofen since it is known both to utilize a known compound for its known purpose and to combine two components taught for the same purpose in order to arrive at a third

composition for the exact same purpose. It is noted that MPEP 2144.07 states "[t]he selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) [...] "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)". The MPEP further states in 2144.05: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

With regard to the specific amounts of the components, it is noted that MPEP 2144.05 states: "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997).

With regard to the limitation of a dosing pump, Pinza teaches a spray composition, wherein it is noted that spray compositions must have a dosing pump in

order to spray the composition. Therefore, though Pinza fails to directly state the nature of the dosing pump, a dosing pump must necessarily be present.

With regard to the exact amount per dose, it is noted that the amount of the composition being utilized is an intended use which one would readily vary depending on the desired treatment and patient (i.e. gender, size, etc).

Response to Arguments

Applicant argues in the remarks filed 09/13/2010 that the prior art references do not teach and/or suggest that the composition is not systemic but merely local. Applicant's argument is not found persuasive since the claims do not recite said limitation. Applicant further argues that in Pinza "there is mention neither to the term "pump" nor "dosing pump" nor "pressure operating pump"" (see remarks, page 10, last paragraph). Applicant's argument is not found persuasive since, as set forth above, though Pinza fails to directly state the nature of the dosing pump, a dosing pump must necessarily be present since the composition is identified as being a spray. Applicant further argues that Pinza discloses a "diclofenac content from 0.07% to 0.14%" (see Remarks, page 11, second to last paragraph), Applicant argues that this differs from the instant range. Applicant's argument is not found persuasive since first, it is noted that the rejection is based on the use of flubiprofen wherein one would, starting with the amount of diclofenac, test the ranges when utilizing an equivalent active ingredient to achieve similar effectiveness. Second, the instant specification evidences that that one looking to match the effectiveness of 0.07% to 0.14% diclofenac would arrive at an amount of approximately 0.15% to 0.8% flubiprofen (see instant specification, page 9,

Table 1). It is noted that MPEP 2144.05 states: "a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)." [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05. Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 716.02 - § 716.02(g) for a discussion of criticality and unexpected results.

Claims 1, 3, 5-14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) as applied to claims 1, 3, 5-12, 14, 16, and 17 above, and further in view of Lundberg et al (U.S. Patent number 6,013,281, patent issued Jan. 11, 2000).

The teachings of Pinza and Caldwell are set forth above.

Pinza fails to directly teach that the composition can comprise either D-glucamine or meglumine.

Lundberg teaches that trometamine, meglumine, and at least one other D-glucamine are all known organic buffer compounds useful in pharmaceutical compositions (See entire document, for instance column 6, lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize any one of, or a combination of trometamine, meglumine, or the at least one other D-glucamine in the invention of Pinza in view of Caldwell. One would have been motivated to do so since it is known both to utilize a known compound for its known purpose and to combine two components taught for the same purpose in order to arrive at a third composition for the exact same purpose. It is noted that MPEP 2144.07 states "[t]he selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) [...] "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)". The MPEP further states in 2144.05: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126

USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Response to Arguments

Applicant argues in the remarks filed 09/13/2010 that for the same reasons as above, the combination of Pinza and Caldwell is improper. For the same reasons as identified above, Applicant's argument is not found persuasive. Applicant further argues that there is not motivation for the combination of the references. Applicant's argument is not found persuasive since it is known both to utilize known compounds for their known purpose and to combine two components taught for the same purpose in order to arrive at a third composition for the exact same purpose. All of the references are directed to pharmaceuticals, and one would have clear motivation to look to art recognized equivalents for a pharmaceutical composition.

New Grounds of Rejection - necessitated by amendment

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) as applied to claims 1, 3, 5-12, 14, 16, and 17 above, and further in view of Hunter et al (U.S. Patent number 6,159,459, patent issued Dec. 12, 2000).

The teachings of Pinza and Caldwell are set forth above.

Pinza fails to directly teach that the composition requires the presence of cetylpyridinium chloride in an amount of 5.0 mg/ml. Hunter teaches an oral composition

wherein the preservatives are taught as being benzoic acid, sodium benzoate, or cetylpyridinium chloride (see entire document, for instance, column 4, lines 34-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize any one of, or a combination of, benzoic acid, sodium benzoate, or cetylpyridinium chloride in the invention of Pinza in view of Caldwell. One would have been motivated to do so since it is known both to utilize a known compound for its known purpose and to combine two components taught for the same purpose in order to arrive at a third composition for the exact same purpose. It is noted that MPEP 2144.07 states "[t]he selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) [...] "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)". The MPEP further states in 2144.05: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). It is noted, as identified in the discussion of Pinza, that sodium benzoate is taught in Pinza to be present in an amount of 5 mg/ml, wherein said 5 mg/ml would

logically be the starting point for the amount of cetylpyridinium chloride, since the art teaches their equivalent function.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643